

### REMARKS

The Official Action dated March 30, 2001 has been carefully considered.

Accordingly, the changes presented herewith, taken with the following remarks, are believed sufficient to place the present application in condition for allowance. Reconsideration is respectfully requested.

By the present Amendment, claim 1 is amended to recite that the isolated nucleic acid, or recombinant version thereof, is human, as originally set forth in claim 1. Claim 2 is amended to include limitations from the specification at page 7, lines 11-13 and to delete reference to "alleles thereof," while claims 8, 9 and 15 have been amended for matters of form. A Version With Markings Showing Changes Made is attached. Claims 42-55 are added. Support for claims 42-46 may be found in the specification at page 5, lines 2-8, while support for claims 47-55 may be found in original claims 4-7 and 13-17, respectively. Finally, claims 10-12, 18-23, 32 and 34-41 have been cancelled. It is believed that these changes do not involve any introduction of new matter, whereby entry is believed to be in order and is respectfully requested.

In the Official Action, the Examiner made the restriction requirement under 35 U.S.C. §121 final. However, with respect to Groups I and II, Applicants submit that the Examiner's restriction requirement is an election of species requirement in view of the generic nature of claims 1-9, 13-17 and 33. Accordingly, reconsideration of the restriction requirement with respect to Groups I and II as an election of species requirement is respectfully requested.

Claims 1-9, 13-17, 32 and 33 were rejected under 35 U.S.C. §101 on the basis that the claimed invention is not supported by either a substantial asserted utility or a well established utility. These claims were also rejected under 35 U.S.C. §112, first paragraph, the Examiner asserting that since the claimed invention is not supported by either a substantial asserted utility or a well established utility, one skilled in the art would not know how to use the

claimed invention. The Examiner asserted that human VDRRg1 is an orphan receptor whose ligand and functional cellular signaling is not known, whereby the method of using the protein lacks well established utility. The Examiner further asserted there is no nexus between unknown properties of the receptor and treatment of diseases.

However, Applicants submit that the present specification establishes utility of the presently claimed invention in accordance with the requirements of 35 U.S.C. §101 and teaches one of ordinary skill in the art how to use the claimed invention in accordance with the requirements of 35 U.S.C. §112, first paragraph. Accordingly, these rejections are traversed and reconsideration is respectfully requested.

More particularly, according to claim 1, the invention is directed to a human isolated nucleic acid, or a recombinant type of the isolated nucleic acid, comprising a contiguous nucleic acid sequence encoding a vitamin D receptor related (VDRR) polypeptide. According to claim 2, the invention is directed to an isolated DNA/nucleic acid according to Fig. 1 (SEQ ID NO:1) or Fig. 7 (SEQ ID NO:3) or substantially the same as that of SEQ ID NO:1 or SEQ ID NO:3, or a recombinant type of the isolated nucleic acid, encoding a VDRR polypeptide.

As set forth at page 1, orphan nuclear receptors (ONRs) serve as potential drug targets for therapeutic invention of common diseases, i.e., the present invention is useful in targeting new therapeutic drugs. More specifically, the Examiner's attention is directed to the specification at page 7, beginning at line 15, which describes the relationship between VDRR $\gamma$  and known vitamin D nuclear hormone receptors, particularly that VDRR $\gamma$  belongs to a sub-family of vitamin D receptors and a VDR-like receptor from *Xenopus Laevis* designated xONR1 or XOR-6. The functions of vitamin D receptors are well known in the art, and one of ordinary skill in the art can therefore easily recognize that the utility of the

claimed invention is similar to the utility of vitamin D receptors, based on the relationship of the claimed invention to known vitamin D receptors.

Thus, contrary to the Examiner's assertion, Applicants have disclosed a nexus between the claimed receptor and the treatment of diseases.

As Applicants disclose the relationship between VDRR $\gamma$  and known vitamin D receptors, and the use of the present invention in drug targeting of new therapeutic drugs, Applicants have disclosed a credible, specific and substantial utility for the claimed invention. Thus, the utility requirements of 35 U.S.C. §101 have been met. Moreover, as Applicants have disclosed a utility for the claimed invention, one of ordinary skill in the art would know how to use the claimed invention without undue experimentation, whereby the requirements of 35 U.S.C. §112, first paragraph, are met. It is therefore submitted that the rejections have been overcome. Reconsideration is respectfully requested.

Claims 1-9, 13-17, 32 and 33 were rejected under 35 U.S.C. §112, second paragraph, as being indefinite. The Examiner asserted that the claims encompass alleles whose metes and bounds are ambiguous.

This rejection is traversed. The term alleles has been omitted from claim 2 and claim 8. Claim 2 now recites an isolated DNA/nucleic acid according to specified sequence ID numbers or substantially the same as that of the specified sequence ID numbers, or a recombinant type of the isolated nucleic acid. The phrase "substantially the same as" is defined at page 7, lines 11-13 and therefore is definite to one of ordinary skill in the art. It is therefore submitted that the rejection under 35 U.S.C. §112, second paragraph, has been overcome. Reconsideration is respectfully requested.

Claims 1-9, 13-17, 32 and 33 were rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventor had possession of the claimed

invention at the time the application was filed. The Examiner asserted that Applicants' claim encompasses a large genus of nuclear receptors from different species of animal and noted that a generic claim to human or mammalian when only rat protein sequence was disclosed did not satisfy the written description specification in *University of California v. Eli Lilly & Company*, 43 U.S.P.Q.2d 1398 (Fed. Cir. 1997).

This rejection is traversed and reconsideration is respectfully requested. More particularly, claim 1 is now directed to a human isolated nucleic acid, or a recombinant type of the isolated nucleic acid, comprising a contiguous nucleic acid sequence encoding a vitamin D receptor related polypeptide. Example 1 describes the identification and isolation of human VDRRg cDNA, Example 2 describes the expression of VDRRg mRNA in human tissue, and Example 4 describes the identification and isolation of human VDRRγ cDNAs encoding multiple N-terminal isoforms. Thus, the specification clearly describes the subject matter of the present claims in such a way as to reasonably convey to one skilled in the relevant art that the inventors had possession of the claimed invention at the time the application was filed, in accordance with the requirements of 35 U.S.C. §112, first paragraph. It is therefore submitted that the rejection has been overcome, and reconsideration is respectfully requested.

Finally, claims 1-9, 13-17, 32 and 33 were rejected under 35 U.S.C. §102(e) as being anticipated by the Kausch et al U.S. Patent No. 5,508,164. The Examiner asserted that Kausch et al disclose the isolation of chromosome from human cells and that claims 1-9, 13-17, 32 and 33 encompass chromosomal DNA because the claims encompass polynucleotide sequence comprising the sequence encoding a polypeptide with SEQ ID NO:2.

However, Applicants submit that the nucleic acids, expression vectors, cells and processes for recombinant production defined by claims 1-9, 13-17 and 33 are not anticipated

by and are patentably distinguishable from the teachings of Kausch et al. Accordingly, this rejection is traversed and reconsideration is respectfully requested.

As noted above, claim 1 is directed to a human isolated nucleic acid, or a recombinant type of the isolated nucleic acid, comprising a contiguous nucleic acid sequence encoding a VDRR polypeptide. According to claim 2, the invention is directed to an isolated DNA/nucleic acid according to Fig. 1 (SEQ ID NO:1) or Fig. 7 (SEQ ID NO:3) or substantially the same as that of SEQ ID NO:1 or SEQ ID NO:3, or a recombinant type of the isolated nucleic acid, encoding a VDRR polypeptide. Claim 13 is directed to an expression vector comprising a nucleic acid according to claim 1, claims 14 and 15 are directed to cells containing a nucleic acid according to claim 1 and an expression vector according to claim 13, respectively, and claims 16 and 17 are directed to processes for recombinant production of a VDRR polypeptide, which processes comprise expressing the nucleic acid of claim 1 in a suitable host cell.

Thus, the nucleic acid of the invention is an isolated nucleic acid, or a recombinant type of the isolated nucleic acid. As set forth in the specification, the term "isolated" indicates that a naturally occurring sequence has been removed from its normal cellular environment and is the predominant nucleic acid or amino acid sequence present (page 7, lines 2-7).

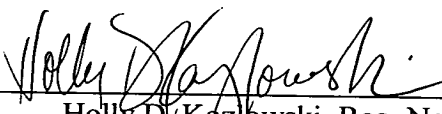
On the other hand, Kausch et al disclose a method for the isolation and sorting of biological materials including chromosomes, segments of chromosomes, cell organelles, or other minute cellular components. At column 10, lines 22-25 referenced by the Examiner, Kausch et al merely disclose that their methods allow the production of large amounts of pure chromosomes for various purposes such as library construction and cloning. Applicants find no teaching or suggestion by Kausch et al relating to an isolated nucleic acid or an isolated DNA/nucleic acid, or a recombinant type of the isolated nucleic acid, as recited in claim 1 or

claim 2. Moreover, in view of Applicants' definition of "isolated" as set forth in the present specification, one of ordinary skill in the art will easily recognize that purified chromosomes as generally taught by Kausch et al do not disclose the isolated nucleic acid, or a recombinant form of the isolated nucleic acid, required by the present claims.

Anticipation under 35 U.S.C. §102 requires the disclosure in a single prior art reference of each element of the claims under consideration, *Alco Standard Corp. v. TVA*, 1 U.S.P.Q.2d 1337, 1341 (Fed Cir. 1986). In view of the failure of Kausch et al to disclose an isolated nucleic acid, or a recombinant form of the isolated nucleic acid, as required by the present claims, Kausch et al do not disclose each element of the claims under consideration and therefore do not anticipate the present claims under 35 U.S.C. §102. It is therefore submitted that the rejection under 35 U.S.C. §102 has been overcome. Reconsideration is respectfully requested.

It is believed that the above represents a complete response to the rejections under 35 U.S.C. §§ 101, 102 and 112, first and second paragraphs, and places the present application in condition for allowance. Reconsideration and an early allowance are requested.

Respectfully submitted,

By   
Holly D. Kozlowski, Reg. No. 30,468  
Attorney for Applicants  
DINSMORE & SHOHL  
1900 Chemed Center  
255 East Fifth Street  
Cincinnati, Ohio 45202  
(513) 977-8568

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**VERSION WITH MARKINGS SHOWING CHANGES MADE**

Claims 1, 2, 8, 9 and 15 are amended as follows:

1. (Twice Amended) A [mammalian] human isolated [or recombinant] nucleic acid, or a recombinant type of the isolated nucleic acid, comprising a contiguous nucleic acid sequence encoding a vitamin D receptor related (VDRR) polypeptide.
2. (Twice Amended) An isolated [or recombinant] DNA/nucleic acid according to Fig. 1 (SEQ ID NO:1) or Fig. 7 (SEQ ID NO:3) [or alleles thereof] or substantially the same as that of SEQ ID NO:1 or SEQ ID NO:3, or a recombinant type of the isolated nucleic acid, encoding a [new] vitamin D receptor related (VDRR) polypeptide.
8. (Third Amendment) The nucleic acid according to claim 1, wherein said nucleic acid sequence is that [given in] of Fig. 1 (SEQ ID NO:1) OR Fig. 7 (SEQ ID NO:3) [or alleles thereof].
9. (Third Amendment) The nucleic acid according to claim 1 [8], wherein said nucleic acid is [the same or] substantially the same as that [given in] of Fig. 1 (SEQ ID NO:1) or Fig. 7 (SEQ ID NO:3).
15. (Amended) A cell containing an expression vector according to claim [14] 13.